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Ukraine

Agricultural Biotechnology Annual

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Report Highlights:

Ukraine intends to keep developing its biotechnology regulatory system in line with that of the European Union. The new draft law under consideration establishes the main biotech reference lab and a Genetically Modified Organism registration and monitoring system. Ukraine still does not have any Genetically Modified Organisms approved for commercial use or production in the country. However, a few reports appeared in the recent year that indicate that Ukrainian origin agricultural products imported by various countries contained Genetically Modified Organisms.

Section I. Executive Summary:

Ukraine still does not have any Genetically Modified Organisms (GMOs) officially registered and allowed for commercial production or for sale in the country. The Government of Ukraine (GOU) has been slowly developing legislation for GMO testing and approval with some new administrative measures instituted in regard to biotechnology existence and use in Ukraine.

In 2010, Ukraine imported over \$50 million in agricultural products that may contain biotech events.

Animal feed that contains biotech soybeans – Monsanto's Roundup-Ready® Soybeans, MON 40-3-2 – did not receive an approval in Ukraine at the time of this report writing. However, this soybean variety is still listed as a temporarily approved feed source.

The GOU requires registration of GMOs that enter the territory of Ukraine. The food labeling law that mandates informing the consumers whether a food item contains or does not contain GMOs – "No GMO" or "Contains GMO" – on product packaging is still in force. A list of food products that require monitoring and testing for biotech content was finally approved in Ukraine in the first quarter of 2011. Food producers are now required to label only products from this list based on the official product's GMO test results.

New draft legislation intends to establish a main GMO reference lab in Ukraine and establish a national GMO registration and monitoring system. This initiative would keep Ukraine in line with the European Union regulation of biotech issues.

Recent media reports indicate that Ukrainian agricultural products imported by other countries tested positive for GM content. One of the latest GMO presence cases reported was in a 6,000 MT shipment of Ukrainian corn to Turkey.

Section II. Plant Biotechnology Trade and Production:

No GM products are officially allowed in Ukraine since none are legally registered in the country according to the recent statement by the Ministry of Health of Ukraine. However, some private sources indicate that over 60% of soybeans grown in Ukraine are GM soybeans along with about 30% of all corn and some 10-20% of sugar beets. Over the years the private estimates of these figures have increased in value.

Trade

In 2010 Ukrainian imports of products that may have contained GM events totaled over \$50 million, which is 16.3% less than in 2009. (see Table 1). The value of imports in these product categories has been dropping since 2008. One of the factors that influenced this decline was a significant downturn in the economy of the country after the financial crisis of 2008. Another equally important factor continued to be the biotech regulation in Ukraine that at the time of this report writing has an incomplete biotech testing and approval framework, is quite complex, and does not favor biotechnology in general.

Table 1 below shows a summary of Ukraine's imports statistics for the major agricultural product categories that

may contain GM events.

Table 1. Ukraine's Imports of Agricultural Products that May Have Been Affected by Ukraine's Biotech Regulation

HS Code	Description	2008		2009		2010		% Change
		Value \$	Share	Value \$	Share	Value \$	Share	2010 /
		million	%	million	%	million	%	2009
110220	Maize (Corn) Flour	0.00	0.0	0.00	0.0	0.01	0.0	11764.4
110313	Maize (Corn) Meal and Groats	0.11	0.1	0.23	0.4	0.27	0.5	_
110423	Processed Maize (Corn)	0.00	0.0	0.00	0.0	0.00	0.0	0.0
120100	Soya Beans	0.93	0.9	0.73	1.2	1.51	3.0	105.8
210310	Soya Sauce	1.59	1.5	1.26	2.1	2.30	4.5	82.0
210610	Protein Concentrates	10.12	9.8	7.14	11.8	7.02	13.8	-1.7
230310	Maize (Corn) Gluten	0.04	0.0	0.05	0.1	0.00	0.0	-100.0
230400	Soya-Bean Meal	76.68	74.0	44.16	72.7	24.93	49.0	-43.5
350400	Protein Isolates	14.14	13.7	7.21	11.9	14.86	29.2	106.2
	Total	103.61	100.0	60.78	100.0	50.90	100.0	-16.3

Source: State Customs Committee of Ukraine

In 2010, the U.S. held an 11.4% market share of these agricultural products imported in Ukraine. Table 2 lists product categories and respective import statistics for the last six years.

Table 2. Imports of U.S. Agricultural Products to Ukraine that May be Affected by Ukraine's Biotech Regulations, Millions U.S. Dollars

HS	Description	2005	2006	2007	2008	2009	2010	% Change 20010/ 2009
110423	Processed Maize (Corn)	0.00	0.00	0.00	0.00	0.00	0.00	0.0
120100	Soya Beans	0.03	0.37	0.07	0.18	0.00	0.17	0.0
210310	Soya Sauce	0.02	0.11	0.14	0.54	0.26	0.71	177.1
210610	Protein Concentrates	0.48	0.40	0.32	1.33	0.22	0.38	69.7
230310	Corn (Maize) Gluten	0.00	0.00	0.00	0.00	0.00	0.00	0.0
230400	Soya-Bean Meal	0.17	0.11	0.84	1.10	7.12	2.67	-62.5
350400	Protein Isolates	1.75	1.39	1.47	0.64	0.07	1.87	2422.1
	Total	2.46	2.39	2.84	3.79	7.68	5.80	-24.44

Source: State Customs Committee of Ukraine

Section III. Plant Biotechnology Policy:

The main legislation that governs biotech events in Ukraine is the <u>Law of Ukraine #1103-16 (Ukr)</u> "On the State System of Biosafety in Creating, Testing, Transporting and Using Genetically Modified Organisms", signed by the President of Ukraine and effective since June 21, 2007. This legislation was amended a number of times with the

latest changes made in January 2010.

In Ukraine, the following GOU entities have been given responsibility for registration, testing, monitoring and approval of the GMO products and products derived with the use of biotechnology:

- The Cabinet of Ministers of Ukraine
- The Ministry of Agrarian Policy and Food of Ukraine
- The Ministry of Education, Youth and Sports of Ukraine (formerly: The Ministry of Education and Sciences of Ukraine)
- The Ministry of Environment and Natural Resources of Ukraine
- o The Ministry of Health of Ukraine
- The State Veterinary and Phytosanitary Service
- The State Inspection of Ukraine for Consumer Rights Protection (formerly: the State Committee of Ukraine for Technical Regulations and Consumer Policy)

The President of Ukraine initiated an administrative reform in late 2010. Various GOU agencies and ministries have been undergoing structural and functional changes. As a result, the State Phytosanitary Service of Ukraine joined the State Committee for Veterinary Medicine that now returned under the jurisdiction of the newly renamed Ministry of Agrarian Policy and Food of Ukraine (MinAg). The functions of MinAg were not changed much in regard to biotech issues regulation. Also, the State Committee of Ukraine for Technical Regulation and Consumer Policy (SCUTRCP) no longer exists. The State Inspection of Ukraine for Consumer Rights Protection was established on the basis of SCUTRCP that also inherited the 9 approved biotech testing labs and at present oversees food product labeling.

For historic data and details on the GOU legislation that was developed and approved in Ukraine in the previous years, please refer to our report: <u>FAS-Kyiv_2010_Biotechnology_Annual_Report_Ukraine.</u>

GM Production and Trade Legislation

The GOU has continued developing the system that governs biotech issues. However, at the time of this report writing, Ukrainian legislation does not allow GMO products or products derived from biotechnology for commercial production or sale in the country. The biotech approval system in Ukraine continues to be incomplete and has been developing slowly and in many ways following the EU lead on the issue.

In January 2011, a list of food products was approved by the GOU that require testing and monitoring for GMO content in Ukraine. The Ministry of Health of Ukraine Order #971 (Ukr) (dated November 9, 2010) lists soybeans and soybean products, corn and products made with corn, potatoes and potato-derived products, tomatoes and tomato products, etc. that are now monitored for GMO events in Ukraine. If any of the food products from this list are present in the ingredient list in any food item that is commercially sold in Ukraine, such foods must undergo GMO testing and certification in Ukraine and be labeled accordingly. A label on a food package that says "Contains GMO" would mean this product is illegal in Ukraine.

On February 2, 2011, the Ministry of Environment and Natural Resources of Ukraine signed <u>Law #36 (Ukr)</u> "On Approval of the Risk Assessment Factors of GMOs' Impact on the Environment" that takes into account a scientific approach to GMO testing and monitoring and lists the following criteria for risk assessment procedures:

- 1) Safety and stability of GMOs and their descendents
- 2) Safety of GMOs in terms of its impact on biochemical and biogeochemical cycles in soil

- 3) Safety of GMOs for animals
- 4) GMO impact on species and varieties and effect of its long-term use
- 5) Research study of interaction of GMOs and different aspects of the environment
- 6) Methods and methodologies of GMO identification, international standards for GMO detection in the environment
- 7) Existence of the preventative measures and environment protecting action plans in case of emergencies and unplanned release of GMOs into the open ecosystem

Importers of seeds for planting faced more scrutiny this year regarding their seed shipments and GMO content. On April 14, 2011, Ukraine notified the World Trade Organization (G/SPS/N/UKR/31/Add.2) on the development of new legislation that would require all planting seeds imported to Ukraine be tested and certified for GMO content by Ukrainian authorities. The draft Order was signed into Law by MinAg later in April but shortly after rejected by the GOU on the grounds of inability to register this legislation. At present, imported seeds are not tested for biotech content on a regular basis in Ukraine.

The Minister of Agrarian Policy and Food of Ukraine in a statement in early 2011 informed the public that the Ministry is interested in the development and strengthening of the domestic planting seed production capacity. He did not clarify whether there will be any preference given to conventional or to biotech seeds production. However, the actions of MinAg and the GOU on biotech issues within the last year indicated that the strategy in this respect is still not well defined. Government policy in Ukraine might turn either for or against biotechnology in the coming months.

GMOs in Animal Feed

No GMO containing feeds were officially approved in Ukraine over the last year. However, Monsanto's Roundup-Ready soybeans MON 40-3-2 remain on the list of temporarily approved sources of feed (MinAg Order #458, dated July 01, 2009).

GOU officials reported that the feeds produced with MON 40-3-2 soybeans that had undergone testing for safety in Ukraine since 2009 did not get approved due to a lack of evidence of the products' safety on its effects on human beings and the environment. However, the testing process for feed products that contain MON 40-3-2 soybeans can be initiated again upon request. More data would have to be provided to conduct further research.

Food Labeling

Food product labeling legislation requires GM content indicated on food products that are sold to Ukrainian consumers. The Government of Ukraine defines GMO presence in a product according to the GOU <u>Resolution</u> #661 (Ukr) as follows:

- 1) Any food product that contains more than 0.9% of GMOs, or if any ingredient in a food product contains GMOs as well as food products that do not contain any GMOs but are produced at least in part with agricultural products that contain GMOs and the total weight of GMO or GMO derived products in a single food product package exceeds 0.9% of its total weight, this food product has to be labeled "Contains GMO".
- 2) If a single package of food product contains zero or less than 0.9% GMOs, this product shall be labeled

"No GMO." Food products that contain ingredients that are listed in the Ukrainian GM-monitored list and possess no labeling are not permitted for sale in Ukraine and are subject to confiscation and fines.

Since early 2011, a list of food products that require testing and monitoring for GM content was limited to 18 product categories. All food products that are made with or contain at least one ingredient from the GMO-monitored list in accordance with the Ministry of Health of Ukraine Order #971, dated November 9, 2010, ought to be tested and certified for biotech content. Such products like table salt or drinking water are no longer required to be labeled according to its GMO content (e.g. "No GMO") as was the case in the past in Ukraine. FAS-Kyiv released a separate report that describes this legislation and its impact in more detail. Please refer to the following link: FAS-Kyiv _GAIN Report_UP1103.

Pending Legislation

At the time of this report writing, there is a draft law pending consideration by the GOU. Draft Law #8494 dated May 12, 2011 "The amendments to the Law of Ukraine "On the State System of Biosafety in Creating, Testing, Transporting and Using Genetically Modified Organisms" on the monitoring the products that contain GMOs." This draft legislation was submitted for the GOU consideration as an initiative of the Cabinet of Ministers of Ukraine with the Prime Minister of Ukraine listed as the author of this draft law.

Draft Law #8494 is intended to:

- introduce a GMO monitoring system in Ukraine
- establish a functional scientific institution to coordinate GMO testing and research in the country

When developing this draft legislation the GOU took into consideration the EU Directive #1830/2003 that concerns monitoring and labeling of the GMOs in food products and in animal feed in the open environment. With these objectives the GOU intended to develop a data collection process and charge a certain agency with the function of developing and maintaining a GMO registration database as well a national reference laboratory. This process, if executed, would allow GMO monitoring at the territory of Ukraine starting with the phase of GMO first entering the country and its first owner to its final users.

In addition, this draft legislation introduces a partial solution to the scientific aspect of biotech research and risk assessment in Ukraine. The draft legislation proposes to establish one main authority in Ukraine for scientific research on GMO. An already established research institution with some expertise in biotech issues would assume the role of GMO reference Laboratory as well as an agency that oversees scientific labs for GMO testing in Ukraine.

Section IV. Plant Biotechnology Marketing Issues:

Marketing of plant biotechnology in Ukraine is still not feasible unless some GM products or products derived with biotechnology are approved for production or trade in the country. Some Ukrainian State institutions conduct research with GMOs in Ukraine but the products obtained as a result of these studies have not been released for public or commercial use and have not been declared safe for the environment.

The situation with public awareness has not changed much in Ukraine since last year. Negative effects of "No GMO" labeling on food products may still be present. Consumers in Ukraine have been getting used to seeing

these labels everywhere in the food markets on packages of all sorts of food items. Some marketers even attempted to modify GMO labels in a way to differentiate their brand. In some cases the message delivered may lead to development of negative impressions among consumers about biotechnology or simply promote GM content labeling into an advertising technique. Below is an example of a scanned copy of ice-cream packaging taken from a product produced and sold in Ukraine. This label looks like it attempted to deliver a message to consumers – 'no brain slug contamination in this product'.



Section V. Plant Biotechnology Capacity Building and Outreach:

In April 2011, FAS organized a digital video conference (DVC) with Ukrainian regulators to discuss science-based

regulation of biotech feeds and veterinary drugs. While the main purpose of the DVC was for Ukrainian regulators to learn about the U.S. approach to regulating biotech-derived feeds, veterinary drugs and vaccines, USDA and FDA answered questions about the Coordinated Framework, molecular testing and traceability.

Upon completion of the Conference Ukrainian participant requested additional information on registration of biotech events in the US. This information was provided to them by the Center for Veterinary Medicine, U.S. Food and Drug Administration and Center for Veterinary Biologics, U.S. Department of Agriculture electronically through the FAS-Kyiv Office.

This digital video conference helps fulfill a joint commitment made by Deputy U.S. Trade Representative (DUSTR) Miriam Sapiro and the Government of Ukraine (GOU) during the last bilateral meeting of the Trade and Investment Council (TIC) in 2010 to convene a working group of experts to discuss the regulation of animal feeds and veterinary drugs derived from biotechnology. Such engagement has also been requested by Dr. Mykola Patsiuk, Deputy Chief of the Chief Veterinary Office (CVO).